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High-level Disinfection and Sterilization – All Steps, Each Time

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Learning Objectives

- Identify specific elements that contribute to high-level disinfection (HLD) or sterilization breaches and identify associated standards that assist in preventing HLD and sterilization breaches from occurring
- Illustrate the role of the Infection Preventionist to high-level disinfection and sterilization processes

Los Angeles Times

**Superbug linked to 2 deaths at UCLA hospital;
179 potentially exposed**

**Superbug outbreak extends to Cedars-Sinai
hospital, linked to scope**

ECRI Top 10 Health Technology Hazards for 2016



- Inadequate cleaning of flexible endoscopes before disinfection can spread deadly pathogens

FDA

- Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication
- FDA: Infections Associated with Reprocessed Duodenoscopes

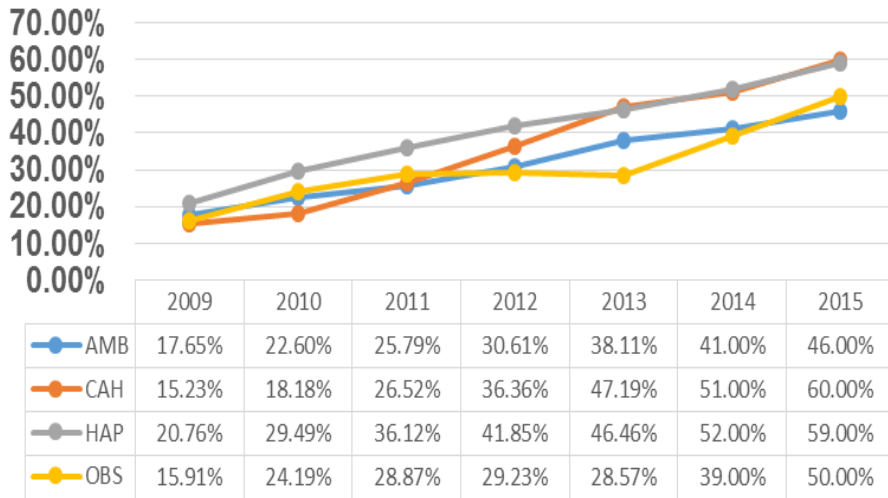
IC.01.03.01 Identifies Risk

- EP1
 - Location, community, population served
- EP2
 - Care, treatment, services provided
- EP3
 - Analysis of activities (data)
- EP5
 - Prioritized identified risks

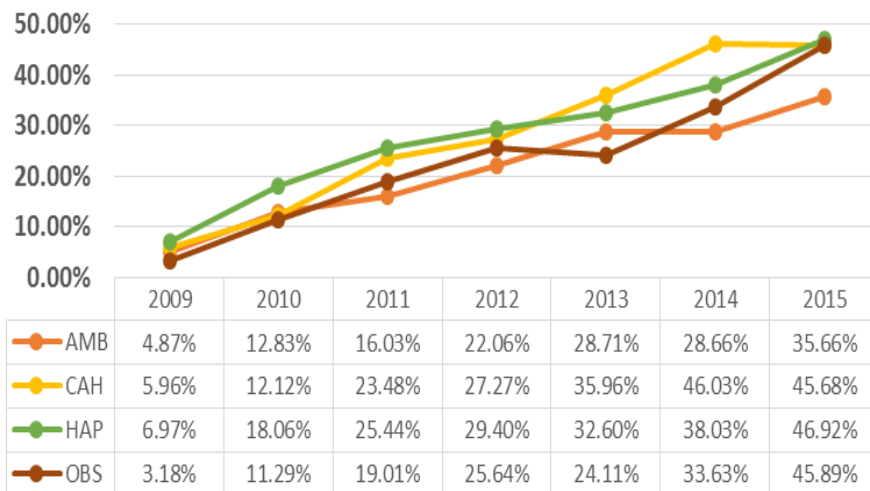
IC.02.02.01

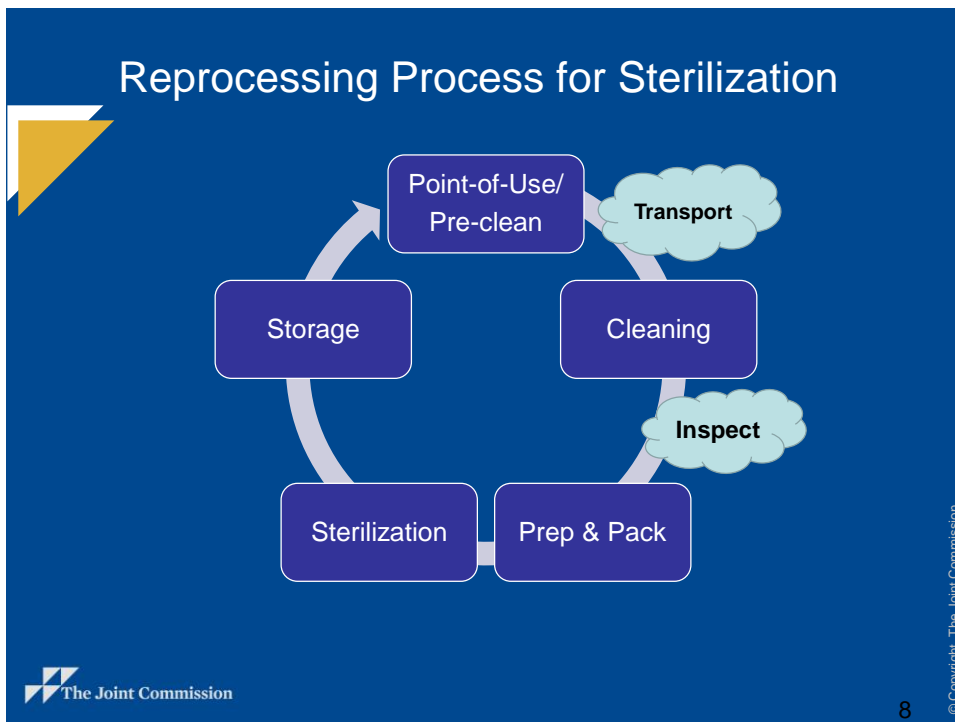
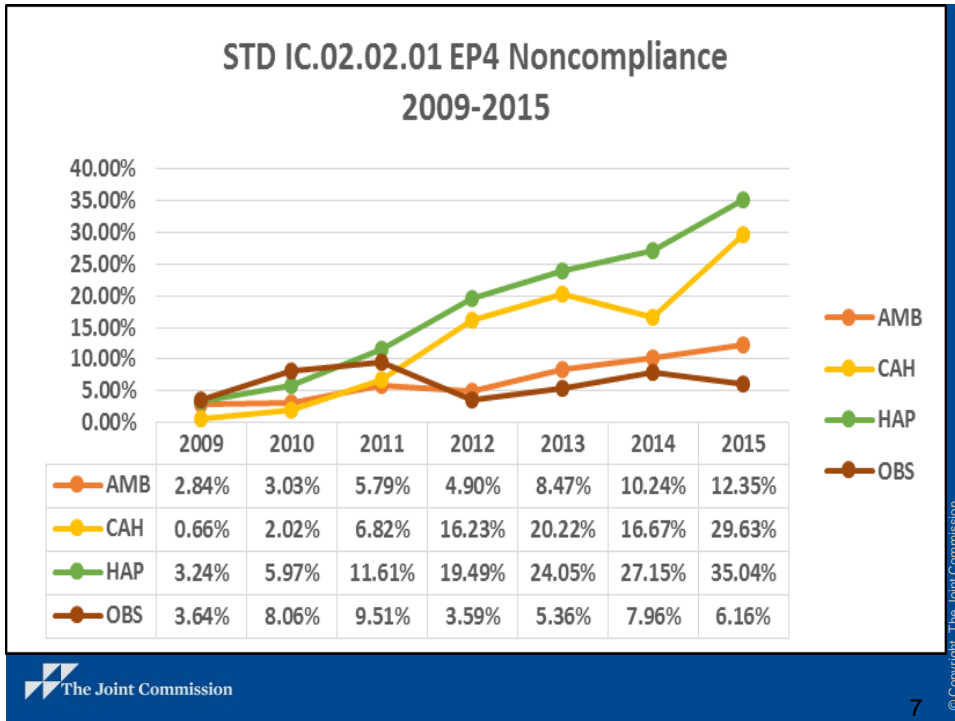
- **IC.02.02.01** The organization reduces the risk of infections associated with medical equipment, devices, and supplies
 - **EP2** Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies
 - **EP4** Storing medical equipment, devices, and supplies

IC.02.02.01 Noncompliance 2009-2015

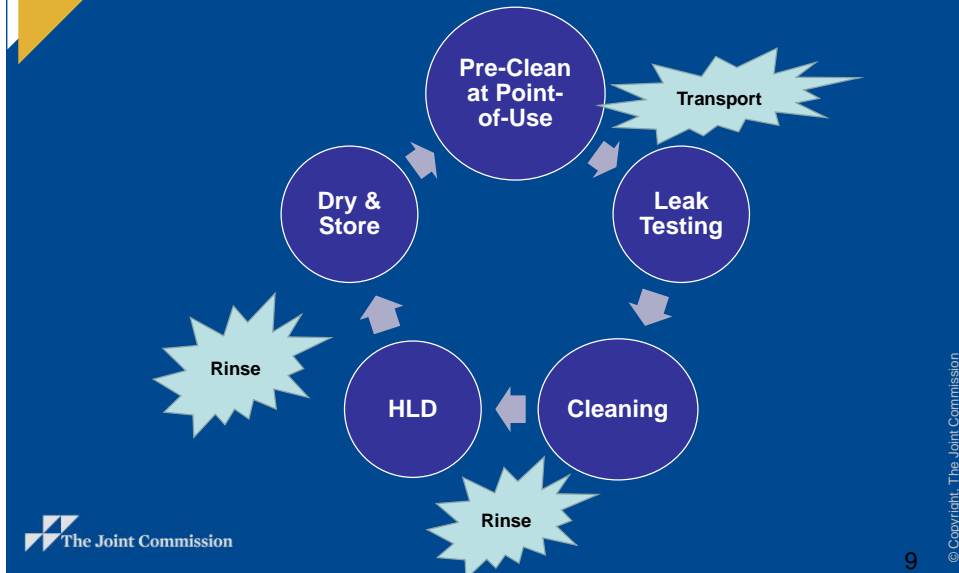


STD IC.02.02.01 EP2 Noncompliance 2009-2015





Reprocessing Process for High-level Disinfection (HLD) - Scopes



Overarching Risks in Reprocessing Medical Equipment, Devices, and Supplies

- ▶ Not adhering to manufacturer's instructions for use (IFUs)
- ▶ Lack of documented staff competency
- ▶ Not following recommended practices or evidence-based guidelines
- ▶ Lack of competent, trained oversight (supervisory)
- ▶ IC involvement

Quality Monitoring of Sterilization

■ Mechanical/Physical Indicators

- Displays, printouts
- Indicates if equipment working properly
- **Not indicator of sterility**

Quality Monitoring of Sterilization

■ Chemical Indicators

- Change color with timed exposure to heat, steam
- Used to show items have gone through sterilization process
- **Not indicator of sterility**

Quality Monitoring of Sterilization



■ Biological Indicators

- Demonstrates bacterial spores on test strips or in vials/containers have all been killed
- **Indicator of sterility**



Quality Monitoring of HLD

- High-level disinfectants are prepared according to manufacturer's instructions for use
 - Length of time
 - Temperature
 - Documentation/logs
 - Test strips – labeled, expiration date, follow instructions for use, correct test strip for solution

Areas of focus: HLD and Sterilization

-  Staff competency and training of HLD and/or sterilization
 - HR.01.02.01 EP1
 - HR.01.04.01 EP4
 - HR.01.05.03 EP1
 - HR.01.06.01 EP's 5, 6
-  Infection Control Practitioner (ICP) knowledge and surveillance of HLD/sterilization processes
 - HR.01.02.01 EP1
 - IC.01.01.01

Areas of focus: HLD and Sterilization

-  Managerial/Supervisor /ICP oversight, leadership knowledge, engagement, and support or lack thereof
 - LD.04.01.05 EP's 1,3,4
-  Ventilation/pressure relationships
 - EC.02.05.01 EP 15
 - Physical layout/Space constraints
 - LD.04.01.11 EP's 2,5

Areas of focus: HLD and Sterilization

- Quality monitoring process and documentation – HLD and sterilization
 - IC.02.02.01 EP2
- Evidence-based guidelines – knowledge and use of
 - IC.01.05.01 EP1

Efficient Workflow – Lean Process

- Encompass reprocessing with related systems
 - Concentrate improvement effort on workflow
- Eliminate variability (waste)
- Automate
- Reduce error

Standardize Work Practices

- Determine process/best practice – Standardize to it
- Involve frontline staff
- Develop P&P
- Train/Re-educate
- Follow-up to assure sustainability and provide feedback

Case Study #1 HLD

- Approximating detergent/cleaning products
- Scope storage – what does that mean?
- What are evidence-based guidelines?
- No IC involvement
- HLD process flow mixing clean and dirty processes.
- No temperature monitoring of HLD
- No documented competency/training of frontline staff
- No competent/trained oversight

Case Study #2

Sterilization

- No pre-cleaning at point-of-use
- Leaving hinged items in the closed position
- No documentation of sterilizer preventative maintenance/cleaning
- No BIs with implant loads
- No IC involvement
- Premature releasing of IUSS
- No competency, training of frontline staff on file
- Manager of OR has oversight with no competency/training

What do you do or say?

- A. Do or say nothing.
- B. Opportunity to re-educate and train staff on HLD and sterilization processes.
- C. Reprocess all probes and instruments involved in these breaches.
- D. Both B and C.



For Consideration

- Internal/System resources
- What can/is immediately corrected
- Leadership response
- Infection Control involvement
- Patient risk, look-back, notification





HLD & Sterilization BoosterPak

- Available for accredited organizations on the HCO Extranet site, including Guest Access
- Applicable to hospitals, critical access hospitals, ambulatory, and office-based surgery settings.

HLD & Sterilization BoosterPak

-  Targeted audience:
 - frontline staff conducting HLD and sterilization
 - Supervisor/manager of HLD and sterilization
 - Infection Preventionists
-  Goal: To ensure HLD and sterilization practices are conducted according to regulatory standards and evidence-based guidelines, in order to minimize the potential risk of infection to patients.

Resources

-  2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities.
-  ANSI/AAMI ST58:2013 Chemical Sterilization and high-level disinfection in healthcare facilities
-  ANSI AAMI ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities
-  ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 (Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Resources

- 2016 SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes
- 2014 APIC Text of Infection Control and Epidemiology. 4th edition.
- 2016 AORN Recommended Practices for Perioperative Nursing – Sterilization and Disinfection
 - o Disinfection – High-level
 - o Flexible Endoscopes – Cleaning and Processing

Questions

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